ATTACHMENT C

REMARKS

By this amendment, Applicants have amended the claims in a manner which overcomes any outstanding rejections and places this application in condition for allowance. In particular, Claim 1 has now been amended to provide the full name of the ClfA protein, Claim 8 has been canceled without prejudice in light of the Examiner's acknowledgement that such antibody fragments are inherently included in Claim 1, Claims 11 and 12 have been amended to refer to Applicants' monoclonal antibody 12-9 which overcomes the objections to these claims, and Claims 27-31 and 33-36 have been canceled without prejudice so that they may be pursued at a later time. Finally, Claims 38-45 have been added to refer to other specific monoclonal antibody embodiments in accordance with the invention. In light of these amendments, the arguments below and the declaration attached hereto, the present application is clearly patentable over the cited references and is in condition for immediate allowance.

In the Official Action, the Examiner noted that the sequence to antibody 35-006 on page 38-39 had inadvertently not been provided with a sequence identifier, and the present amendment overcomes this objection. Similarly, Claim 1 was objected to for not including the full name of the ClfA protein, and Applicants have amended this claim to provide the full name. Next, Claim 8 was objected to by the Examiner as unnecessarily duplicative of Claim 1, and Applicants have hereby cancelled Claim 1 without prejudice based on the Examiner's confirmation that antibody fragments having the same binding specificity of an antibody which binds to the ClfA protein is included in

and/or is inherent in Claim 1. Finally, Claim 28 was objected to, but this objection is moot since Applicants have canceled this claim without prejudice.

In the Official Action, the Examiner rejected Claims 11-14, 27-31 and 33-36 under 35 U.S.C. § 112 as failing to meet the written description requirement, and under 35 U.S.C. § 112 for enablement.[1] These rejections are made moot in that Claims 11 and 12 have been amended, and new Claims 38-45 have been added, to specifically refer to the heavy and light chain combinations as disclosed in the present application, and these embodiments are unquestionably clear and well disclosed in the application so that they could be made and used by one of ordinary skill in the art. The remaining claims 13-14, 27-31 and 33-36 have been canceled without prejudice. Accordingly, the claims as they presently stand are clearly proper under 35 U.S.C. § 112, and the Examiner's objections under this provision have been traversed and should be withdrawn.

Finally, in the Official Action, the Examiner rejected Claims 1-10, 15, 19, 23, 24 and 37 under 35 U.S.C. § 103(a) as being unpatentable over Foster et al. U.S. Pat. No. 6,008,341, on the Examiner's assertion that despite the fact that the reference did not teach the making of monoclonal antibodies which recognized ClfA (or region Clf33), the reference "provided a suggestion for, and renders obvious the making of antibodies to the Clf33 region." This rejection, insofar as applied to the claims as amended, is respectfully traversed for the reasons as stated below and in the attached Declaration of Dr. Joseph M. Patti, Ph.D.

---

[1] The Examiner's rejection of Claim 26 on enablement grounds is not discussed in the rejection, and it is assumed that the Examiner intended to reject Claims 27-31 and not 26-31 on these grounds.

As an initial matter, as indicated above, despite the obviousness rejection, the Examiner recognizes that the cited Foster reference does not "actually teach the making of monoclonal antibodies to the identified protein region." Moreover, the Examiner seems to indicate that any monoclonal antibody could be prepared at any time, and that such antibody would be protective as the Examiner stated was "suggested" in the Foster reference. However, to the contrary, it is in fact the case that even one skilled in the art **cannot** state with certainty which monoclonal antibodies will be successfully produced, much less provide protection against infection. As shown in the attached Declaration of Dr. Joseph M. Patti. Ph.D. ("Patti Dec.", it is well understood in the art that some monoclonal antibodies may be protective while others are not, even if there are similarities between the targets of the antibodies.

Even further, it was unexpectedly shown that the antibodies in accordance with the present invention were in fact protective against infection by *staphylococcal* bacteria. As shown in the attached Declaration and articles, the monoclonal antibody 12-9 as described and claimed in the present application was tested for its ability to immunize mice against infection from *Staphylococcus aureus,* and mice treated with the anti-ClfA monoclonal antibodies had significantly greater survival times over mice treated with controls. Additional studies evidenced the repeatability of the protection, and confirmed the surprising efficacy of the mAb in accordance with the invention. As indicated in the attached Declaration, the unexpected beneficial results obtained by use of the monoclonal ClfA antibodies of the present application were not only the first report of a successful monoclonal antibody to ClfA, they were the first report of a

monoclonal antibody against **any** cell surface protein from *S. aureus* that demonstrated significant in vivo protection. See Patti Dec., ¶¶ 4-6.

Accordingly, contrary to the position of the Examiner, it indeed was unforeseen that any monoclonal antibody to the ClfA protein, or to the particular Clf33 region, would result in a monoclonal antibody that could protect against challenge from Staphylococcal bacteria. As such, the invention as embodied in the present claims is clearly unobvious and thus patentable over the cited Foster et al. reference. Applicants thus submit that the Examiner's rejection on the basis of the Foster reference is respectfully traversed and should be withdrawn.

In the Official Action, the Examiner also rejected dependent claims 16, 17, 26 and 32, but none of the cited references, either singly or in combination, disclose or remotely suggest the subject matter in Applicants' claim 1 or its dependent claims, and these claims are patentable for at least the reasons set forth with regard to claim 1 above.

In light of the amendments and arguments as set forth above, as well as the attached Declaration of Dr. Patti,[2] Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

END REMARKS

---

[2] An executed copy of this Declaration will follow shortly.